

REMARKS

By way of the present response, claims 1-26 are pending. Claims 23-26 have been newly added and Claims 21-22 have been withdrawn without prejudice or disclaimer as allegedly being directed to a non-elected invention. Applicants reserve the right to pursue the withdrawn claims in a continuing application. Support for the foregoing amendment can be found throughout the Specification and the claims as originally filed, for example, in the Specification at page 22, line 16 - page 23, line 5. No new matter has been added by way of the present amendment.

I. Rejection under 35 U.S.C. § 112, First Paragraph, Enablement

Claims 1-16 and 18-20¹ stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way so as to enable those skilled in the art to make and/or use the invention commensurate in scope with the claims. Office Action mailed January 25, 2007 ("Final Office Action") at pages 3-4. In rejecting the claims, the Office asserts that the specification "while enabling for a method of treating pancreatitis and/or relieving the pain caused by pancreatitis in a mammalian subject comprising administering to said subject an effective amount of the amylin analog 25, 28, 29 Pro-h-amylin...does not enable any person in the art for preparing a method for treating pancreatitis and/or relieving pain caused by pancreatitis comprising administering all amylin analogs." *Id.*

Applicants thank the Office for the acknowledgment that the specification is enabling for a method of treating pancreatitis and/or relieving the pain caused by pancreatitis in a mammalian subject comprising administering to said subject an effective amount of the amylin analog 25,28,29 Pro-h-amylin. *Id.* Given this acknowledgement by the Office, Applicants fail to understand why claims 9-11 remain rejected under 35 U.S.C. § 112, first paragraph. The Office has indicated on the record that the specification is enabling for a method of treating pancreatitis and/or relieving the pain caused by pancreatitis in a mammalian subject comprising administering to said subject an effective amount of the amylin analog 25,28,29 Pro-h-amylin. Non-Final Office Action at pages 2-3; Final Office Action at pages 3-4. This is exactly what

Applicants have provided for in claims 9-11. Moreover, the Specification provides methods of treating pancreatitis and/or relieving the pain caused by pancreatitis by administering an amylin or an amylin analog to subjects. Specification, for example, at page 5, line 20 - page 8, line 2; page 9, lines 5 - 24; page 11, Table 1; and Examples I -III. Given this, Applicants respectfully submit that the claimed invention could be practiced by one of ordinary skill in the art without undue experimentation.

The Office has not met the evidentiary burden to impose an enablement rejection. A specification that discloses how to use a claimed invention “must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein.” *In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995), *quoting In re Marzocchi*, 439 F.2d 220, 223, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971) (emphasis in original). The Office has provided neither evidence supporting the rejection nor any explanation of why the specification allegedly fails to enable the claimed invention.

As such, it is submitted that Applicants have provided considerable direction and guidance, and have presented working examples such that it is well within the level of ordinary skill in the art to practice the invention without undue experimentation. The Office has not provided sufficient evidence to cast doubt on the guidance provided in the specification. Rather, the Office has provided generalizations regarding a lack of predictability in the art and the need for some experimentation.

Even assuming, *arguendo*, that the Office’s generalization regarding the unpredictable state of the art is accepted, the conclusion that undue experimentation would be required to practice the claimed method is inconsistent with the current state of the law. Specifically, the law provides that experimentation is not necessarily undue simply because it is complex, if the art typically engages in such experimentation. *See In re Certain Limited-Charge Cell Culture Microcarriers*, 221 U.S.P.Q. 1165, 1174, (Int’l Trade Comm’n 1983) *aff’d. sub nom.*, *Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 U.S.P.Q. 428 (Fed. Cir. 1985).

¹ Claims 2-13 depend from Claim 1; Claims 15-20 depend from Claim 14.

In rejecting claims 1-16 and 18-20, the Office asserts that the specification does not teach a method of treating pancreatitis and/or relieving the pain caused by pancreatitis by administering all amylin analogues to subjects. Final Office Action at pages 4-5. This standard is legally incorrect. There is no requirement to provide **all** of the ways that the claimed invention can be practiced. MPEP § 2164.01(b). The enablement requirement is satisfied as long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim. *Id.* Applicants have satisfied this requirement by providing methods of treating pancreatitis by administering amylin and numerous amylin analogs to subjects. Specification, for example, at page 5, line 20 - page 8, line 2; page 9, lines 5 - 24; page 11, Table 1; and Examples I -III.

Applicants disagree with the Office's assertion that the specification "has failed to provide guidance or working examples whereby applicant prepares a method for treating pancreatitis and/or relieving the pain caused by pancreatitis comprising administering all amylin analogs." Final Office Action at page 5. Again, this standard is legally incorrect. Applicants are not required to describe all embodiments of their invention in working examples. MPEP § 2164.02. Moreover, "[c]ompliance with the enablement requirement of 35 § U.S.C. 112, first paragraph, does not turn on whether an example is disclosed." *Id.* Rather, because the specification provides an adequate number of working examples and guidance regarding a method of treating pancreatitis by administering an amylin or amylin analog to a subject, Applicants have satisfied their burden under 35 § U.S.C. 112.

Given the disclosure, Applicants respectfully submit that one of ordinary skill in the art would have the requisite skill to choose amylin or amylin analogs capable of treating pancreatitis. Specification, for example, at page 5, line 20 - page 8, line 2; page 9, lines 5 - 24; page 11, Table 1; and Examples I -III. Applicants have sufficiently described the claimed invention such that one of skill in the art in light of the specification would be able to practice the invention commensurate in scope with the claims. Taken in combination, such disclosure provides adequate direction, including working examples, to teach the skilled artisan how to make and use the claimed invention without undue experimentation.

Accordingly, for at least these reasons, it is submitted that the claims are sufficiently enabled under 35 U.S.C. § 112, first paragraph, and withdrawal of this rejection is respectfully requested.

II. Rejection under 35 U.S.C. § 103

Claims 1-16 and 18-20 stand rejected under 35 U.S.C. § 103 as allegedly being obvious over Young *et al.* (U.S. 5,677,279) in view of Braganza *et al.* (U.S. 5,196,402) and Jorgensen *et al.* (U.S. 4,370,317). In rejecting the claims, the Office has asserted that it would be *prima facie* obvious, given the teachings of Young *et al.* in view of Braganza *et al.* and Jorgensen *et al.*, to administer^{25,28,29} Pro-h-amylin to a subject to treat a painful disorder. Final Office Action at page 5. Applicants disagree.

To establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of skill in the art, to modify the reference or to combine reference teachings. There must also be a reasonable expectation of success. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on the applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Applicants respectfully assert that the Office has failed to establish a *prima facie* case of obviousness because the Office has not provided an adequate explanation of the suggestion or motivation to combine the teachings of Young *et al.* with either Braganza *et al.* or Jorgensen *et al.* The Office alleges that one of ordinary skill in the art would have been motivated to administer the composition discussed by Young *et al.* to a subject in order to treat pancreatitis. Applicants respectfully disagree.

Whatever else Young *et al.* disclose, Young *et al.* does not disclose or teach treating pancreatitis by administering an amylin or an amylin analog to a mammalian subject. Neither Braganza *et al.* nor Jorgensen *et al.* provide motivation to modify Young *et al.* by administering an amylin or an amylin analog to a subject in order to treat pancreatitis. Moreover, whatever else Braganza *et al.* and Jorgensen *et al.* describes, neither reference describes an amylin or an amylin analog, let alone^{25,28,29} Pro-h-amylin. At best, Braganza *et al.* and Jorgensen *et al.* generally describe pancreatitis as a "painful condition." Braganza *et al.* at column 1, lines 11-15.

However, this is not enough. Neither Braganza *et al.* nor Jorgensen *et al.* provide any specific motivation whatsoever for administering the amylin or an amylin analogs to a subject for the treatment of pancreatitis. Additionally, by advocating the use of S-Adenosyl-Methionine for the treatment of pancreatitis, Braganza *et al.* actually teaches away from administering an amylin or an amylin analog to a subject for the treatment of pancreatitis. Braganza *et al.* at column 2, lines 23 - 42. That is, having read Braganza *et al.*, one of ordinary skill in the art would be motivated to administer S-Adenosyl-Methionine to a patient, not an amylin or an amylin analog. There is no indication in Braganza *et al.* that there is any sort of advantage or desirability of administering any drug outside of S-Adenosyl-Methionine to a patient for the treatment of pancreatitis. Neither Jorgensen *et al.* nor Young *et al.* adequately account for this deficiency.

Moreover, neither Braganza *et al.* nor Jorgensen *et al.* disclose or fairly suggest administering an "effective amount" of amylin or amylin analog to a subject. Applicants respectfully assert that the Examiner ignored this point when maintaining the rejection. Given the fact that neither Braganza *et al.* nor Jorgensen *et al.* disclose administering an "effective amount," one of ordinary skill in the art at the time the invention was made would not have the requisite motivation or knowledge to administer an "effective amount" of an amylin or an amylin analog to a patient in order to treat pancreatitis.

"The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990) (Claims were directed to an apparatus for producing an aerated cementitious composition by drawing air into the cementitious composition by driving the output pump at a capacity greater than the feed rate. The prior art reference taught that the feed means can be run at a variable speed, however the court found that this does not require that the output pump be run at the claimed speed so that air is drawn into the mixing chamber and is entrained in the ingredients during operation. Although a prior art device "may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so." 916 F.2d at 682, 16 USPQ2d at 1432.)." MPEP § 2143.01. The motivation suggested by the Office, that combining Young *et al.* with Braganza *et al.* and Jorgensen *et al.* would result in an "improve[d] method of...treating the painful method of pancreatitis in a mammalian subject," does not suggest the desirability of the claimed

invention. Final Office Action at page 6. The Office does not even explain in what way the method would be improved or why one of ordinary skill in the art at the time the invention was made have the motivation to combine Young *et al.* with Braganza *et al.* and Jorgensen *et al.* Applicants therefore respectfully disagree with the Office's assertion that one of skill in the art would have been motivated to combine the teachings of Young *et al.* with Braganza *et al.* and Jorgensen *et al.*

Applicants also respectfully assert that the Office has failed to establish a *prima facie* case of obviousness because there would have been no reasonable expectation of success, at the time the invention was made, in combining the teachings of Young *et al.* with Braganza *et al.* or Jorgensen *et al.* Applicants respectfully point out that there is no reasonable expectation in either Young *et al.*, Braganza *et al.*, or Jorgensen *et al.*, that administering an amylin or an amylin analog to a subject would successfully treat pancreatitis. Without such motivation, the claims are improperly rejected under 35 U.S.C. § 103.

In conclusion, the Office has failed to meet even one of the requirements to establish a *prima facie* case of obviousness.

In light of these remarks, Applicant respectfully requests withdrawal of this rejection of claims 1-16 and 18-20 under 35 U.S.C. § 103 for purportedly being unpatentable over Young *et al.* in view of Braganza *et al.* and Jorgensen *et al.*

CONCLUSION

In view of the above, each of the presently pending claims is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding objection and rejections of the claims, and to pass this application to issue. The Examiner is encouraged to contact the undersigned at (202) 942-5186 should any additional information be necessary for allowance.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "D R Marsh", written in a cursive style.

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